THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 59 (90/003,488)
Paper No. 41 (90/003,989)

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte NOVAMEDIX LIMITED

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Appeal No. 97-3680
Reexamination Control Nos. 90/003,488 and 90/003,989[1]

_____

ON BRIEF

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[1] Requests filed July 11, 1994 (Control No. 90/003,488) and October 4, 1995 (Control No. 90/003,989) by Kinetic Concepts, Inc. for the reexamination of U.S. Patent No. 4,696,289, issued September 29, 1987, based on Application 06/889,376, filed August 1, 1996. The resulting reexamination proceedings were ordered merged on February 1, 1996 (see Paper No. 24 in Control No. 90/003,488 and Paper No. 8 in Control No. 90/003,989). According to the appellant: Application 06/889,376 is a continuation-in-part of Application 06/763,686, filed August 8, 1985, now U.S. Patent No. 4,614,180, issued September 30, 1986, and reissued as U.S. Patent No. Re. 32,939 on June 6, 1989, based on Application 07/194,438, filed May 16, 1988, and a continuation-in-part of Application 06/794,443, filed November 4, 1985, now U.S. Patent No. 4,614,179, issued September 30, 1986, and reissued as U.S. Patent No. Re. 32,940 on June 6, 1989, based on Application 07/194,519, filed May 16, 1988; Application 06/763,686 is a continuation-in-part of Application 06/621,499, filed June 18, 1984, now abandoned; Application 06/794,443 is a continuation-in-part of Application 06/751,150, filed July 2, 1985, now abandoned, which is a division of Application 06/621,499.

Before CALVERT, McQUADE and CRAWFORD, Administrative Patent Judges.

McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Novamedix Limited appeals from the examiner's final rejection of claims 1 through 21, 23 and 33 through 60, all of the claims pending in these merged reexamination proceedings involving U.S. Patent No. 4,696,289. Our decision in this appeal applies to each proceeding.

The record indicates that U.S. Patent No. 4,696,289, as well as related and commonly assigned U.S. Patent Nos. Re. 32,939, Re. 32,940, and 4,721,101, are currently the subject of litigation, styled Novamedix, Ltd. v. Kinetic Concepts, Inc. and KCI New Technologies, Inc., Civil Action No. SA-92-CA-1077, in the United States District Court for the Western District of Texas, San Antonio Division.[2] The record also indicates that these four patents had been the subject of litigation, styled Novamedix Limited v. NDM

[2] Kinetic Concepts, Inc. also has requested two reexaminations in each of U.S. Patent Nos. Re. 32,939, Re. 32,940 and 4,721,101. Control Nos. 90/003,487 and 90/003,987 for U.S. Patent Re. 32,940 have resulted in the issuance on December 3, 1996 of Reexamination Certificate B1 Re. 32,940. Control Nos. 90/003,486 and 90/003,988 for U.S. Patent No. Re. 32,939 are currently on appeal to this Board (Appeal No. 97-2135). Control Nos. 90/003,489 and 90/003,990 for U.S. Patent 4,721,101 also are currently on appeal to this Board (Appeal No. 97-2766).

Acquisition Corp. et al., Civil Action No. C-3-94-251, in the United States District Court for the Southern District of Ohio, Western Division at Dayton. In the latter case, the court entered a final judgment on consent decreeing, inter alia, that each of the claims in the four patents "is valid and enforceable" (see Paper No. 30½ in Control No. 90/003,488 and Paper No. 11 in Control No. 90/003,989).

The invention at issue in the instant appeal relates to a method for promoting venous pump action in the leg of a patient by stimulating a physiological venous pump mechanism in the sole of the foot in a manner which differs from that in which the pump mechanism is stimulated naturally by normal ambulation. As explained by the inventors, Arthur M. N. Gardner and Roger H. Fox,

> [w]e have discovered a venous pump mechanism in the sole of the human foot, which under normal walking conditions for the foot, serves to return blood from the leg into the abdomen with no assistance from muscular action; additionally, we have discovered that when this pump mechanism is stimulated in a particular manner which is not analogous to normal walking conditions for the foot, an overall improvement in blood flow specifically includes enhanced arterial flow [patent specification, column 1, lines 44 through 52].

The inventors' departure from normal ambulatory conditions involves the application of forces to the foot for a holding period of time which is not present in normal ambulation. Claim 1 is illustrative and reads as follows:

1. The method of promoting venous pump action in the leg of a living body, which method comprises simultaneously applying (a) upward and spreading force at longitudinally spaced plantar regions of the sole of the foot, said regions being essentially

limited by and between the ball and heel of the foot and (b) downward force at the region of the midtarsal joint, said forces being applied in a cyclical pattern of a relatively rapid-time period in which said forces are rapidly increased to a predetermined upper force limit, then said upper force limit is retained for a holding period of time before relaxation for a period substantially exceeding an application time, whereby said application time includes both said rapid increase time period and said holding time period and the arch of the foot is caused to flatten periodically and [this] thus to stretch and neck down the internal local sectional area of the veins of the lateral plantar complex, with resulting venous-pump action.

The prior art references relied upon by the examiner as evidence of obviousness are:

Jensen	1,492,514	Apr. 29, 1924
Nicholson et al. (Nicholson)	3,901,221	Aug. 26, 1975
Gardner et al., British Patent Document (Gardner/Fox)	2,141,938	Jan. 9, 1985

Rastgeldi, Selahaddin, "II. Intermittent Pressure Treatment of Peripheral Vascular Diseases, A Survey of Sixteen Years Personal Experience," Opuscula Medica, Supplementum XXVII, pages 19-49, 1972 (Rastgeldi)

Gaskell, P. and Parrott, J. C. W., "The Effect of a Mechanical Venous Pump on the Circulation of the Feet in the Presence of Arterial Obstruction," Surgery, Gynecology & Obstetrics, Volume 146, pages 583-592, April 1978 (Gaskell/Parrott)

Claims 1 through 21, 23 and 33 through 60 stand rejected under 35 U.S.C. § 103 as follows:

a) claims 1 through 3, 5 through 10, 11/5, 11/7, 12, 13/5, 13/7, 15/8-10, 16/8-10, 18/6, 18/9, 20/6, 20/9, 21/5, 21/7, 21/8, 23/5, 23/7, 23/8, 45/5, 45/8, 46/7, 46/10, 47/5, 47/8, 48/7, 48/10, 49/6, 49/9, 50, 51/6, 51/9 and 52 as being unpatentable over

Gardner/Fox in view of Gaskell/Parrott or Nicholson;

b) claims 4, 11/4, 13/4, 17, 19, 21/4 and 23/4 as being unpatentable over Gardner/Fox in view of Gaskell/Parrott or Nicholson, and further in view of Jensen;

c) claims 1 through 3, 5 through 10, 11/5, 11/7, 12, 15/8-10, 18/6, 18/9, 20/6, 20/9, 21/5, 21/7, 21/8, 23/5, 23/7, 23/8, 33 through 39, 41/35, 41/38, 42/35, 42/38, 43/33, 43/36, 44/33, 44/36, 45/5, 45/8, 46/7, 46/10, 47/5, 47/8, 48/7, 48/10, 49/6, 49/9, 50, 51/6, 51/9, 52, 53/33, 53/36, 54/34, 54/37, 55/33, 55/36, 56/34, 56/37, 57/34, 57/37, 58/35, 58/38, 59/34, 59/37, 60/35 and 60/38 as being unpatentable over Gardner/Fox in view of Rastgeldi;

d) claims 13/5, 13/7, 14, 16/8-10 and 40/33-38 as being unpatentable over Gardner/Fox in view of Rastgeldi, and further in view of Gaskell/Parrott;

e) claims 4, 11/4, 17, 19, 21/4 and 23/4 as being unpatentable over Gardner/Fox in view of Rastgeldi, and further in view of Jensen; and

f) claim 13/4 as being unpatentable over Gardner/Fox in view of Rastgeldi and Jensen, and further in view of Gaskell/Parrott.

Reference is made to the appellant’s main brief (Paper No. 38 in Control No. 90/003,488 and Paper No. 21 in Control No. 90/003,989) and to the examiner’s answer (Paper No. 39 in Control No. 90/003,488 and Paper No. 23 in Control No. 90/003,989) for

the respective positions of the appellant and the examiner with regard to the merits of these rejections.[3]

In rejecting a claim, an examiner bears the initial burden of presenting a factual basis establishing a prima facie case of unpatentability. In re Oetiker, 977 F.2d 1443, 1445-46, 24 USPQ2d 1443, 1444-45 (Fed. Cir. 1990); In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 788 (Fed. Cir. 1984). If this burden is met, the burden of coming forward with a showing of facts supporting the opposite conclusion shifts to the applicant. After such rebuttal evidence is submitted, all of the evidence must be considered anew, with patentability being determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument. Of course, if the examiner's initial showing does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent. Id.

With regard to rejections made under 35 U.S.C. § 103, our reviewing court stated in In re Huang, 100 F.3d 135, 138, 40 USPQ2d 1685, 1687-88 (Fed. Cir. 1996):

> A claimed invention is unpatentable if the differences between it and

[3] The record (Paper No. 54 in Control No. 90/003,488 and Paper No. 36 in Control No. 90/003,989) indicates that the "Patent Owner's Second Amendment After Filing Notice of Appeal" (Paper No. 37 in Control No. 90/003,488 and Paper No. 20 in Control No. 90/003,989) and the "Patent Owner's Reply to Examiner's Answer" (Paper No. 43 in Control No. 90/003,488 and Paper No. 27 in Control No. 90/003,989) have not been entered into the record. Accordingly, we have not considered the arguments and evidence contained in these papers in reviewing the merits of this appeal.

> the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103 (1994). The ultimate determination as to whether or not an invention is obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 567 (1966).

Within this framework, the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 425-26, 208 USPQ 871, 881-82 (CCPA 1981). A conclusion of obviousness may be based on the common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). In this regard, skill is to be presumed on the part of the artisan. In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985).

Gardner/Fox, the examiner's primary reference, discloses a medical appliance designed to stimulate the physiological venous pump mechanism in the sole of a human foot by replicating forces applied to the foot during normal ambulatory motion.

Figure 1 illustrates an embodiment of the appliance which includes an inflatable bag 1 shaped to engage only the plantar arch of the foot, a sling 4 for securing the bag to the foot and a pump apparatus 3 for inflating the bag. As explained by Gardner/Fox,

> [i]n use of the appliance when secured to a foot as shown in Figure 1, the pump apparatus 3 operates rapidly to inflate the bag 1 which then applies a pumping pressure to the sole 10 of the foot 11, and also urges the ball and heel of the foot away from each other, thus flattening the plantar arch as would occur if the foot 11 was placed on the ground during normal ambulation, thereby stimulating venous blood-flow. A valve arrangement (not shown) in the pump apparatus 3 then allows the bag 1 to deflate whereafter the bag 1 is again inflated, the inflation/deflation cycle being repeated as long as treatment with the appliance is required.
>
> Preferably inflation of the bag 1 is effected in two seconds or less to provide a satisfactory pumping action, while deflation of the bag 1 can take as long as is necessary for the return of blood to the veins of the foot 11.
>
> The treatment thus provided simulates walking on the foot 11, and thereby improves venous blood circulation in a person being treated who would normally be unable to walk or possibly even stand on the foot.
>
> As a modification of the above described appliance, the valve arrangement in pump apparatus 3 can be dispensed with, the pump apparatus serving only for cyclic inflation of the bag, and at least the surface of the bag 1 in contact with the foot 11 being formed with air leakage orifices thereby to be permeable to air, or being made of a material which is inherently permeable to air . . . . Such a surface can be provided as will give the required period for deflation of the bag 1 [page 1, lines 77 through 113].

Figures 2 and 3 illustrate an alternative embodiment of the appliance for use within a plaster cast. In this embodiment, the bag wraps around the foot so as to engage both the plantar arch and the instep.

Gardner/Fox also discloses that either of the foregoing embodiments may be secured to a patient's foot by conventional footwear such as a boot (see page 2, lines 15 through 19).

As acknowledged by the examiner (see page 5 in the answer), Gardner/Fox does

not meet the various limitations in independent claims 1 through 10 and 33 through 38 requiring the force(s) or shrinking confinement applied to the foot to be retained, held or maintained for a period of time. The examiner's reliance on Gaskell/Parrot, Nicholson and/or Rastgeldi to cure this deficiency in Gardner/Fox with respect to the claimed invention is not well taken.

Gaskell/Parrott discloses a mechanical venous pump for treating severe arterial obstructions in a patient's foot. As described in this reference,

> [t]he venous pump consisted of the arrangement illustrated in Figure 1. The foot, covered by a length of stockinette, was inserted into a boot made of a single layer of transparent flexible vinyl plastic sheet. The toe of the boot was fitted with a large metal ring which was made airtight by the insertion of a rubber stopper. The stopper carried tubes for the inflation of the boot and for monitoring pressures. At the ankle, the boot was circled by a pneumatic cuff shaped to fit snuggly on a cone. The cuff and the boot were connected to their own individual air pressure reservoirs. To operate the pump, the cuff was first inflated to the pressure desired in the boot. The pressure reservoir serving the boot was then opened with an available pressure above that in the cuff. The boot was quickly inflated to the pressure set by the pressure in the cuff, with the excess flow of air escaping from the boot under the cuff. Both cuff and boot were deflated again after 2 seconds. The pressure on the foot within the boot was thus regulated by the pressure in the cuff. An electronic timer controlled the time and period of inflation of the cuff or boot individually but in a linked and synchronized manner [page 583].

According to Gaskell/Parrott, "[a] brief inflation of the boot empties the veins of the foot, and the venous pressure remains reduced until the veins are refilled by forward flow of blood from the arteries" (page 583). To evaluate the effectiveness of the boot in reducing venous pressure, Gaskell/Parrott tested it using the following variables: "compression

pressures, ranging from 40 millimeters of mercury below to 40 millimeters of mercury above the venous pressure at the foot, compression periods of 0.5 to 4.0 seconds in increments of 0.5 second, compression frequencies of once every 5, 10, 15, 20 and 30 seconds" (page 584). Figure 3 depicts the results of tests using different compression pressures wherein "the foot was compressed every 15 seconds for 2 seconds" (page 586). Among other things, Gaskell/Parrott generally found

> that a compression pressure several millimeters of mercury higher than the maximum venous pressure at the foot was necessary for most efficient pressure reduction. A compression period of 2 seconds was the minimum at which one could be sure of an adequate pressure reduction, 1 second was often too short and periods longer than 2 seconds were unnecessary and reduced efficiency [pages 587 and 588].

Nicholson discloses a boot for treating circulatory deficiencies in a patient's leg in order to increase the flow of blood through the veins. According to Nicholson, this result can be obtained "by applying pressure through a pressure garment with a rise time of at least 10 mm of mercury per second and a holding time at the level of at least 30 mm of mercury for at least 8 seconds. A cycle period of one minute is near optimum" (column 1, lines 51 through 55). The boot 26 communicates with a pressure tank 30 via hoses 28. The operation of the boot is controlled by a cyclic controller 34 for applying and releasing pressure in accordance with the graph shown in Figure 1. As described by Nicholson,

> FIG. 1 is a graph of pressure at the cyclic controller output in accordance with the preferred pressure cycle. When the pressure line is connected to the boot by operation of a valve at time zero, curve portion 10

> indicates a rapid rise in less than 4 seconds to greater than 30 mm of mercury. The pressure then climbs gradually above 40 mm of mercury as indicated by curve 11 until 10 seconds is reached at which point the pressurizing valve is closed and the exhaust valve opening to the atmosphere is opened so that at 12 seconds the pressure has dropped below 10 mm as depicted by curve 12. For the following 48 second time period, depicted by curve 14, no pressure is applied allowing the blood veins to refill. This cycle repeats at 60 second intervals [column 2, lines 14 through 27].

As for the pressure inside the boot, Nicholson states:

> FIG. 4 shows pressure measured inside a boot during a controller pressure cycle according to FIG. 1. The rise time inside the boot is 40 mm Hg. in approximately 4 seconds as shown in curve 35. The fall time shown by curve 36 is likewise a little slower falling to 10 mm Hg. in about 2 seconds and then curving exponentially to 0 over the next 8 seconds.
>
> While the invention has been described in accordance with a preferred embodiment, some latitude in the operation of the cycle is desirable depending on specific patients and conditions. A rapid boot pressure rise to at least 30 mm of mercury produces near optimum results when extended over 3 seconds. With particularly sensitive patients, this rise may be extended out to 5 seconds to reduce discomfort. Similarly, the maximum pressure attained is desirably between 40 and 50 mm of mercury, but a peak of 30 mm of mercury is sufficient for most cases. A range of 9 to 15 seconds is acceptable for the time interval between the beginning of pressure application and the onset of pressure release. For maximum effect it is desirable to delay the next application of pressure until the venous flow has returned to its normal equilibrium point, however, this differs with the individual patient and may vary within a fairly wide range with a total period between the cyclical commencement of pressure application being anywhere from about 40 to 80 seconds. A period of 60 seconds is suitable for most cases [column 2, line 67 through column 3, line 26].

Rastgeldi discloses a method and apparatus for treating circulatory conditions such as ischemia by the cyclical application of pressure to a patient's leg (see pages 38 through 43). The method involves the use of a venous occlusion cuff applied about the upper thigh, and cyclically inflatable cuffs applied about the lower thigh, calf and foot. The inflatable cuffs communicate with a source of pressure which functions to (1) inflate the cuffs from 0 mm Hg to a suprasystolic pressure of, for example, 210, 230 or 240 mm Hg, (2) maintain the suprasystolic pressure for holding period of, for example, 5 or 6 seconds,

(3) deflate the inflatable cuffs back to 0 mm Hg, and (4) repeat the process at intervals of, for example, 20, 21 or 22 seconds (see Figures 10 through 12).

With regard to the acknowledged failure of Gardner/Fox to meet the various limitations in independent claims 1 through 10 and 33 through 38 requiring the force(s) or shrinking confinement applied to the foot to be retained, held or maintained for a period of time, the examiner first states that

> [t]he [Gardner/Fox] patent didn't go into such details because the exact method of use is well within the realm of the artisan of ordinary skill. One of ordinary skill could take the Gardner/Fox device and develop any specific timing or pressure which is desired for any specific type of use. There appears to be no unobviousness to exactly how one uses the Gardner/Fox device [answer, page 5].

The examiner then goes on to conclude that

> [i]t would have been obvious to modify the inflation method of Gardner/Fox with the holding period and length of the relaxation period taught by either Gaskell/Parrott or Nicholson et al. in order that the pressure is rapidly applied to the foot, held for a period of time and then relaxed for a period of time so that blood flow in a patient's limb is most effectively stimulated for a specific intended use. It is felt that the exact parameters are considered to be obvious considerations dependent [on] intended use and obvious experimentation in view of the teachings of Gaskell/Parrott and Nicholson et al. for each of these references teaches a rapid inflation, a holding period and deflation of the pressure applicator [answer, page 6].

In a similar vein, the examiner states that "[i]t would have been obvious to modify the method of applying pressure to the foot of a patient for assisting circulation as taught by Gardner/Fox with the holding period and pressure levels taught by Rastgeldi so that

circulation in the extremity will be increased" (answer, page 8).

As indicated above, the Gardner/Fox reference pertains to a medical appliance which stimulates the physiological venous pump mechanism in the sole of a human foot by replicating forces applied to the foot during normal ambulatory motion. Thus, it is not surprising that this reference fails to meet the limitations in independent claims 1 through 10 and 33 through 38 requiring the force(s) or shrinking confinement applied to the foot to be retained, held or maintained for a period of time since such a holding period of time is not present in normal ambulation according to the appellant's patent specification. Indeed, given the stated objective of the Gardner/Fox appliance and its intended method of use, this reference actually teaches away from a method embodying the holding period of time required by claims 1 through 10 and 33 through 38.

Moreover, the devices and methods disclosed by Gaskell/Parrott, Nicholson and/or Rastgeldi for improving circulation differ substantially from those disclosed by Gardner/Fox. For example, none of these secondary references shares Gardner/Fox's appreciation that a physiological venous pump mechanism exists in the sole of a foot, that this pump mechanism is naturally stimulated by normal ambulatory motion and that the conditions of such ambulatory motion can be simulated by an inflatable device. Although the Rastgeldi device includes an inflatable cuff disposed about the sole and instep of the foot, Rastgeldi gives no indication that this cuff is even inherently capable of functioning in

the manner desired by Gardner/Fox.

In this light, it is not apparent, nor has the examiner cogently explained, how or why the combined teachings of Gardner/Fox in view of Gaskell/Parrott, Nicholson and/or Rastgeldi would have suggested the method recited in independent claims 1 through 10 and 33 through 38, and in claims 11 through 21, 23 and 39 through 60 which depend therefrom. The explanations of the appealed rejections reproduced above indicate that the examiner has improperly resorted to speculation, unfounded assumptions and/or hindsight reconstruction to supply the deficiencies in the basic prior art combinations advanced in support of these rejections. Jensen, applied in some of the rejections for its disclosure of a static arch support, does nothing to overcome the fundamental flaws in these basic prior art combinations.

Thus, the prior art evidence relied upon by the examiner to support the standing 35 U.S.C. § 103 rejections of claims 1 through 21, 23 and 33 through 60 fails to establish a prima facie case of obviousness with respect to the subject matter recited in these claims. This being so, it is not necessary to delve into the evidence of non-obviousness of record which is relied upon by the appellant in this appeal.

In light of the foregoing, we shall not sustain any of the standing 35 U.S.C. § 103 rejections on appeal.

The decision of the examiner is reversed.

REVERSED

IAN A. CALVERT)
Administrative Patent Judge)
)
)
) BOARD OF PATENT
JOHN P. McQUADE)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
MURRIEL E. CRAWFORD)
Administrative Patent Judge)

Appeal No. 97-3680
Reexamination Control Nos. 90/003,488 and 90/003,989

JPM/caw

For patent owner:

Roy C. Hopgood & Steven Judlowe
HOPGOOD, CALIMAFDE, KALIL & JUDLOWE
60 EAST 42ND STREET
NEW YORK, NY 10165

For reexamination requester:

Charles W. Hanor
AKIN, GUMP, STRAUSS, HALTER & FELD
1500 NATIONSBANK PLAZA 300
CONVENT STREET
SAN ANTONIO, TX 78205